Problems in development of Halfkine Institute for Training Research and Testing

2202. SHRI SURESH KALMADI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Government are facing problems to develop Halfkine Institute for Training, Research and Testing and Halfkine Bio-pharmaceutical Corporation Ltd. with the help of Russian technology; and

(b) what action Government propose to take in the matter?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) and (b) The information is being collected and will be laid on the Table of the House.

Clearance for Marketing of Ethyloestrenol, Methandienone and Stanozolol

2203. SHRI P. N. SUKUL: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Ethyloestrenol, Methandienone and Stanozolol have been cleared for marketing in the country;

(b) if so, when were these drugs cleared and what are the details of indications for which each is used;

(c) whether any precaution is to be taken for any of these drugs;

(d) what are the counter indications of each drug;

(e) whether any of these drugs have hazard effect;

(f) if so, the details thereof;

(g) what are the details of corrective steps in that regard; and

(h) what was the quantity of each drug imported in the country during the last two years along with names of importers, quantity imported by each, CIF price per kg. and source of import?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Yes, Sir.

(b) The enabolic steroids Methandienone, Stanozolol, Ethylestrenol which are indicated for chronic debilitating diseases particularly in old age, osteoporosis, refractary and aplastic anaemia selected cases of prepubertal growth retardation were cleared for marketing in February, 1963, June, 1965 and June, 1962 respectively.

(c) to (f) Precautions side effects and contraindications for these drugs are at Statement-I.

(g) Precautions to be observed while prescribing anabolic steroids are given in Statement-I.

(h) As per information available with this Ministry the quantity of each drug imported during the last two years along with the C.I.F. value is at Statement-II.

Statement-I

Precautions

1. Anabolic Steroids should be administered only intermittently not exceeding three months at a time. If no beneficial effect is observed during this period, the drug should be discontinued. The interval between two cources of treatment should not be less than 3 months.

2. While using Anabolic steroids in the pre-pubertal age group, there

should be very close monitoring and supervision by means of parameters like bone-age, development of secondary sex characteristics and growth velocity chart. If there is evidence of epiphyseal maturation, at any stage, as shown by follow-up X-ray, the treatment with Anabolic Steroids should be discontinued.

3. The use of Anabolic Steroids in atheletes does not improve the work performance of the atheletes.

4. The Anabolic Steroids should not be given as food substitutes under any circumstances. These drugs exert their optimal effect only when adequate portein and caloric intake in the patients is ensured and not otherwise.

Contra-Indications:

1 Prostatic careinoma.
2. Pregnancy.
3. Breast carcinoma in males.
4. Liver disfunction.
5. Congestive cardic failures.

Side-effects

Increase in Nitrogen retention, skeletal weight, sodium and water retention, oedema, increased vascularity of the skin hypercalaemia, increased growth of the hane.

The long term use of Anabolic Steroid can produce cancer specially of prostate, liver and the breast.

In female patients the use of anabolic steroids can produce virilism and this effect can be irreversible when prolonged treatment is given.

Statement—II

Quantity of Methandienone, Stanozolol and Ethylestrenol imported during the year 1986-87, 1987-88 *alongwith c.i.f. value*

S. No.	Name of the Drug	Year	Quantity imported in kgs.	c.i.f. value
1.	Methandienone	1986-87	368	32,67,441
		1987-88	358	31,79,267
2.	Stanozolol	1986-87	14.1	7,92,763
		1987-88	22	11,41,242
3.	Ethyestrenol	1987-88	Nil	Nil

Drug Manufacturers not Having Testing and Quality Control Facilities

2204. SHRI P. N. SUKUL: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that a number of drug manufacturers do not have testing and quality control facilities available with them;

(b) what is the total number of drug and formulations manufacturing companies in the country, who do not possess such facilities;

(c) whether it is a fact that due to this reason, sub-standard medicines are on the increase;

(d) whether it is also a fact that these companies get their samples tested at private laboratories;

(e) if so, the names of such laboratories; and

(f) what is the total number of Government Laboratories in the country and how many samples were sent to these laboratories and what was the